UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
FORT MYERS DIVISION

RINA WATLER,

Plaintiff,

v. Case No: 2:22-cv-30-WFJ-MRM

NOVARTIS PHARMACEUTICALS CORPORATION,

Defendant.

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ORDER DENYING MOTION TO DISMISS

This matter comes before the Court on Defendant Novartis Pharmaceuticals Corporation's Motion to Dismiss, Dkt. 15, Plaintiff Rina Watler's complaint, Dkt. 1. Plaintiff filed a response in opposition, Dkt. 28, to which Defendant replied, Dkt. 35. Defendant also contemporaneously filed a Motion to Take Judicial Notice of multiple Food and Drug Administration ("FDA") documents central to Plaintiff's complaint. Dkt. 21. Plaintiff did not oppose that motion. Dkt. 31. Upon careful consideration, and in taking judicial notice of the cited FDA documents, the Court denies Defendant's Motion to Dismiss.

BACKGROUND

Defendant manufactures and sells Beovu, a vascular endothelial growth factor ("VEGF") inhibitor used to treat Wet Age-Related Macular Degeneration, or

Wet AMD. Dkt. 1 ¶¶ 8−9, 19. Wet AMD is a chronic eye disease in which visual impairments result from the leakage and accumulation of fluid in the retina. *Id.* ¶ 20; Dkt. 15 at 2. The FDA approved Beovu for use in October 2019. Dkt. 1 ¶ 23. Plaintiff, a Florida resident, was prescribed and received three Beovu injections in 2020. *Id.* ¶¶ 5, 13. These ocular injections took place on January 6, 2020, February 28, 2020, and April 22, 2020. *Id.* ¶ 13.

Plaintiff contends that she developed severe vision problems following her third Beovu injection in April 2020. *Id.* She was diagnosed with retinal vascular occlusion approximately two months later. *Id.* Retinal vascular occlusion is a condition characterized by an obstruction of the retina's venous or arterial system, which causes vision loss that can be severe and permanent. *Id.* ¶ 32. This condition can develop from retinal vasculitis, which involves the inflammation of the retinal vessels. *Id.* Plaintiff asserts that Beovu's product labeling contained no warnings of retinal vasculitis or retinal vascular occlusion when she received her three injections. *Id.* ¶ 61. Shortly after Plaintiff's final injection, however, Beovu's product labeling was updated on June 9, 2020, to include warnings regarding the risk of both conditions. *Id.* ¶ 59.

Plaintiff alleges that Defendants knew of these hazards months before it updated Beovu's product labeling. *Id.* ¶ 57−58. She contends that Defendant began receiving adverse event reports regarding retinal vasculitis and retinal vascular

occlusion in November 2019 and continued to receive such reports through April 2020. *Id.* ¶¶ 44−50. Plaintiff also points to post-marketing data and peer-reviewed medical literature that she states demonstrate the causal relationship between Beovu and retinal vasculitis and retinal vascular occlusion. *Id.* ¶¶ 62−83. According to Plaintiff, this information amounted to "newly acquired information" that should have prompted Defendant to immediately add warnings to Beovu's product labeling pursuant to the federal "changes being effected" ("CBE") regulation, which does not require the FDA's prior approval. *Id.* ¶ 57−58 (citing 21 C.F.R. § 601.12(f)(6)). Plaintiff contends that Defendant instead misrepresented the safety of Beovu and failed to warn physicians and the public of Beovu's propensity to cause serious ocular injuries. *Id.* ¶¶ 2−4.

Based on the above, Plaintiff brings a four-count complaint against Defendant under Florida law. Count I asserts a claim of strict liability under a failure to warn theory. *Id.* ¶¶ 85−98. Plaintiff contends that, despite knowing of the risks of using Beovu, Defendant failed to provide sufficient warnings and instructions to consumers and physicians regarding Beovu's adverse effects. *Id.* ¶¶ 85−86. In Count II, Plaintiff alleges negligence. *Id.* ¶¶ 99−106. Plaintiff claims that Defendant failed to exercise reasonable care in, inter alia, advertising, developing, and researching Beovu and communicating its risks. *Id.* ¶¶ 99−102. Plaintiff next asserts fraudulent misrepresentation in Count III. *Id.* ¶¶ 107−41. According to

Plaintiff, Defendant knowingly made false representations and material omissions regarding Beovu's safety and side effects. *Id.* ¶¶ 107−10. Lastly, Count IV is a negligent misrepresentation claim. *Id.* ¶¶ 142−54. Plaintiff alleges that Defendant negligently made material misrepresentations and omissions regarding the safety and side effects of Beovu. *Id.* ¶¶ 142−44.

Defendant now moves to dismiss Plaintiff's complaint pursuant to Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim, Dkt. 15, while also asking this Court to take judicial notice of four FDA documents, Dkt. 21.

LEGAL STANDARD

To survive a Rule 12(b)(6) motion to dismiss for failure to state a claim, a plaintiff must plead sufficient facts to state a claim that is "plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). This standard does not require detailed factual allegations, but it demands more than an unadorned accusation. *Id.* When considering a Rule 12(b)(6) motion to dismiss, a court accepts all factual allegations of the complaint as true and construes them in the light most favorable to the plaintiff. *Pielage v. McConnell*, 516 F.3d 1282, 1284 (11th Cir. 2008). Moreover, courts should limit their "consideration to the well-pleaded factual allegations, documents central to or referenced in the complaint, and matters judicially noticed." *La Grasta v. First Union Sec., Inc.*, 358 F.3d 840, 845 (11th Cir. 2004).

ANALYSIS

The Court first addresses Defendant's Motion to Take Judicial Notice. Defendant asks this Court to take judicial notice of four FDA documents: (1) Beovu's October 2019 product labeling, (2) Beovu's FDA approval package, (3) Beovu's June 2020 product labeling, and (4) the FDA's "Questions and Answers" document regarding its adverse event reporting system. Dkt. 21. at 2. Because these documents are FDA publications and accessible on the FDA website, the facts within the documents "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b). In considering Defendant's dismissal motion, it is proper for this Court to take judicial notice of these documents that are central to Plaintiff's complaint.

Turning to Defendant's Rule 12(b)(6) Motion to Dismiss, Defendant asserts that Plaintiff's complaint fails for multiple reasons. First, Defendant contends that Plaintiff's claims are preempted because she has not alleged newly acquired information that would have allowed Defendant to unilaterally change Beovu's product labeling via the CBE regulation. Dkt. 15 at 7. Next, Defendant posits that Count III is preempted as a "fraud-on-the-FDA" claim. *Id.* at 18. Defendant lastly avers that the fraudulent statements alleged in Counts III and IV have not been pled with particularity as required by Rule 9(b). *Id.* at 20.

Based on the standard for dismissal, Defendant's motion must be denied.

Viewing the facts in the light most favorable to Plaintiff, as this Court must at this stage, the complaint states plausible claims for relief and puts Defendant on clear notice of what it must defend.

Contrary to Defendant's first assertion, Plaintiff has adequately alleged newly acquired information to support her claims that Defendant had the ability to change Beovu's product labeling under the CBE regulation without prior FDA approval. In her complaint, Plaintiff points to 104 post-marketing adverse event reports of patients who experienced retinal vasculitis or retinal vascular occlusion prior to Plaintiff's final Beovu injection on April 22, 2020. Dkt. 1 ¶¶ 44−50. Plaintiff alleges that many of these adverse event reports contained causal contributions to patients' use of Beovu. *Id.* ¶ 51. Plaintiff also cites other new adverse information, including a March 2020 report in medical literature regarding a patient's development of retinal vascular occlusion after receiving Beovu injections and Defendant's publishing of a "safety signal" for retinal vasculitis and retinal vascular occlusion on April 8, 2020, which Defendant surely considered internally before publication.[1] *Id.* ¶¶ 39, 56. Just two months after issuing the safety signal, Defendant updated the warnings on Beovu's product labeling to

[1] Pursuant to FDA guidance, "safety signals generally indicate the need for further investigation, which may or may not lead to the conclusion that the product caused the event." Dkt. 15 at 16 (quoting FDA, Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment 4 (Mar. 2005), https://www.fda.gov/media/71546/download).

account for these precise injuries. *Id.* ¶ 59.

In three consolidated cases concerning similar claims, the District of Nebraska denied motions to dismiss similar to the one presently before this Court. *See Harris v. Novartis Pharms. Corp.*, No. 4:21-cv-3013 (D. Neb. Sept. 8, 2021). Like the timeline alleged by Plaintiff here, the timeline put forth in *Harris* showed new adverse event reports and other data preceding the plaintiffs' Beovu injections. *Id.* at *10. The *Harris* court determined that those instances of new adverse information amounted to newly acquired information such that the plaintiffs' claims were not preempted. The Court reaches the same conclusion here, as Plaintiff has sufficiently alleged newly acquired information such that her claims are not preempted on this basis.

Additionally, while Defendant contends that Plaintiff's Count III fraudulent misrepresentation claim is preempted as a fraud-on-the-FDA claim under *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), the Court disagrees. In *Buckman*, the Supreme Court held that state-law claims premised on a fraud-on-the-FDA theory are preempted because they conflict with "the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." 531 U.S. at 350. However, unlike this case, *Buckman* concerned a clear fraud-on-the-FDA claim in which the plaintiffs alleged that the defendant made false representations to the FDA. *See id.* at 343. Here, Count III contains

multiple factual allegations that Defendant made fraudulent representations of Beovu's safety *to physicians and consumers* after receiving FDA approval. *See, e.g.*, Dkt. 1 ¶¶ 123−28. Viewing the allegations within Plaintiff's Count III as a whole, the Court finds that the claim reads more like a standard Florida pharmaceutical failure-to-warn case, suggesting that *Buckman* is inapplicable.

Though Defendant relies on a Central District of California decision to support its contention that *Buckman* preemption applies here, the Ninth Circuit recently reversed the district court on that point. *See Rayes v. Novartis Pharms. Corp.*, No. 21-55723, 2022 WL 822195 (9th Cir. Mar. 18, 2022), *aff'g in part, rev'g in part*, No. 21-201-JGB-KKX, 2021 WL 2410677 (C.D. Cal. June 11, 2021). The Ninth Circuit explained that the *Rayes* plaintiff's state-law claims were based on the defendant's "duty to warn consumers and physicians, not its duty to submit accurate data to the FDA." *Id.* at *1. So, too, are Plaintiff's nearly identical allegations when Count III is given a full and fair reading. The Court finds that Count III as pled is not preempted by *Buckman*.

Finally, though Defendant posits that Plaintiff has failed to plead with particularity her allegations of fraud within Counts III and IV, the Court finds that Plaintiff has met her pleading burden under Rule 9(b). Pursuant to Rule 9(b), a party alleging fraud "must state with particularity the circumstances constituting fraud[.]" This requirement serves the "twin purposes" of providing notice to a

defendant of a plaintiff's claims of fraud and protecting that defendant's reputation against "spurious charges" of fraudulent behavior. *Wagner v. First Horizon Pharm. Corp.*, 464 F.3d 1273, 1277 (11th Cir. 2006). Plaintiff's Counts III and IV do not frustrate these purposes. Both counts contain specific factual allegations of fraud that put Defendant on clear notice of the claims against it. Considering these specific factual allegations, Counts III and IV are not spurious charges from which Defendant's reputation must be protected.

CONCLUSION

For the foregoing reasons, Defendant's Motion to Dismiss, Dkt. 15, is **DENIED**. Defendant should file its answer to Plaintiff's complaint, Dkt. 1, within **fourteen (14) days**.

DONE AND ORDERED at Tampa, Florida, on March 31, 2022.

/s/ William F. Jung
WILLIAM F. JUNG
UNITED STATES DISTRICT JUDGE

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